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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,755	10/30/2001	Toshihiro Shimizu	2522 US2P	1478

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,755	Applicant(s) SHIMIZU ET AL.	
	Examiner Susan Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-36 and 38-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-36 and 38-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Corrected Filing Receipt filed 02/20/02, Fee filed 02/21/02, Information Disclosure Statement filed 10/30/01, and Preliminary Amendment A filed 10/30/01.

Information Disclosure Statement

The information disclosure statement (IDS) filed 10/30/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. There are no copies of the listed A4-A10 references in the submitted IDS. Accordingly, the IDS has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11-36, and 38-49 are rejected as being anticipated by claims 1-45 of U.S. Patent No. 6,328,994 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, *i.e.*, orally disintegrable dosage form comprising acid-labile physiologically active substance. The physiologically active substance of the instant application is generic, and therefore, permits different species of acid-labile active substance, including lansoprazole. Furthermore, applicant also uses lansoprazole as a physiologically active substance (see examples).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 32-36, and 38-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Shimizu et al. US 5,824,339 (339).

Shimizu teaches effervescent composition comprising a core-shell powder surrounding a fine granular core spray-coated with water-soluble polymer, physiologically active substance, and enteric coating layer (see abstract and column 3). The fine granular core having average diameter of about 250 μm , includes crystalline

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cellulose and 50-70% lactose beads (columns 4-5). The composition further comprising additives, such as, crystalline cellulose, mannitol, lactose, magnesium or calcium carbonate, and mixture thereof (column 6, lines 36-51). The physiologically active substance layer further comprising 0.1 to about 50% low-substituted hydroxypropylcellulose (columns 6-7).

The above 102(a) rejection will be reconsidered and withdrawn provided that, applicant submit translation of the filed foreign applications.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-9, 11-22, 24, 31-36, and 38-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimizu et al. (339).

Shimizu teaches effervescent composition comprising a core-shell powder surrounding a fine granular core spray-coated with water-soluble polymer, physiologically active substance, and enteric coating layer (see abstract and column 3). The fine granular core having average diameter of about 250 μm , includes crystalline cellulose and 50-70% lactose beads (columns 4-5). The composition further

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comprising additives, such as, crystalline cellulose, mannitol, lactose, magnesium or calcium carbonate, and mixture thereof (column 6, lines 36-51). The physiologically active substance layer further comprising 0.1 to about 50% low-substituted hydroxypropylcellulose (I-HPC), (see columns 6-7). The amount of active substance is disclosed throughout the examples.

The examiner notes that Shimizu is silent as to the teaching of the tablet hardness. However, it is the position of the examiner that the particular tablet hardness is inherent since Shimizu is using the same ingredients to obtain the same result desired by the applicant, *i.e.*, tablet dosage form of effervescent fine granules containing acid-labile drug.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-36, and 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. (339).

Shimizu is relied upon for the reasons stated above. In the case that applicant can overcome the above 102(a/e) rejections, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to obtain the claimed invention because the reference teaches the advantageous result in the use of coated granules of

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acid-labile active substance. The expected result would be effervescent tablet dosage form of fine granules containing acid-labile drug, which will provide accurate controlled release rate.

Claims 1-9, and 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. (339), in view of Shimizu et al. US 6,299,904 (904). The examiner relies on the date of the foreign application of Shimizu (904), which is 05/27/97. The translation copy will be provided in the next office action communication.

Shimizu (339) is relied upon for the reasons stated above. The reference is silent as to the teaching of tablet hardness.

Shimizu (904) teaches quick disintegrable solid pharmaceutical composition comprising 0.01 to 70% acid-labile active ingredient; 5 to 97% of one or more water-soluble sugar alcohols, e.g., erythritol, maltitol, or sorbitol; and low-substituted HPC having hydroxypropoxyl group contents of 7.0 to 9.9% (abstract, and columns 2-5). The composition further comprising about 3 to 50% of crystalline cellulose (columns 5-6). The solid dosage form is disintegrated within 50 seconds and having hardness of about 2 to about 20 kg (columns 7-8). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify Shimizu (339), using the sugar alcohol in view of the teaching of Shimizu (904), because the references teach the advantageous results in the use of sugar alcohol to obtain a disintegrable oral dosage form. The expected result would be a disintegrable tablet having quick dissolution rate and appropriate hardness strength.

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Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Makino et al., and Cousin et al. are cited as being of interest for the teaching of compositions comprising benzimidazole.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached from Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 4:30 pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
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